Alan Goldhammer, PhD
Associate Vice President,
US Regulatory Affairs

PhRMA

January 29, 2001

Ms. Nancy M. Ostrove
Center for Drug Evaluation and Research
(HFD-42)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket Number 00N-1269; Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels; Proposed Rule; 65 Federal Register 81082; **Request for Extension of the Comment Period**

Dear Ms. Ostrove:

The Pharmaceutical Research and Manufacturers of America (PhRMA) requests the comment period for this proposed rule be extended for an additional **90** days. FDA's effort to make the drug label more easily understandable is laudable, but raises significant legal, compliance, and implementation issues for the pharmaceutical industry. We are in the process of formulating PhRMA's response to this important initiative and have identified a number of issues that may require further discussion with the FDA. As you are aware the appropriate time for such discussions is while the docket is open for comment. Thus, PhRMA requires the extra time to insure that we are able to provide the Agency with the best input on this issue.

Thank you in advance for considering this request. Please contact me if you have any questions.

Sincerely,

Alan Goldhammer